K011374

MAY 2 9 2001

510(k) Summary

Vestil Manufacturing Corporation's
510(k) Premarket Notification
Jewel MPS Manual Wheelchair

Applicant's Name, Address, Telephone, and Fax Numbers

Vestil Manufacturing Corporation
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 219.668.5677 Fax: 219.668.8967

Preparer's Name, Address, Telephone, Fax Number, Contact Name, and Date Prepared

Vestil Manufacturing Corporation
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 219.668.5677 Fax: 219.668.8967

Contact Person: Rick Michael
Sales Manager

Date Prepared: April 30,2001

Manufacturer's Name, Address, Telephone, and Fax Numbers

Magic International Pty. Ltd.
48 Henderson Road, Clayton North
Victoria 3168, Australia
Phone: 011.613.9561.9722 Fax: 011.613.9561.9733

Name of Device and Name/Address of Sponsor:

Jewel MPS Mechanical Wheelchair

Vestil Manufacturing Corporation
900 Growth Parkway
PO Box 507
Angola, IN 46703
Phone 219.668.5677 Fax: 219.668.8967

Common or Usual Name
Manual Wheelchair

Classification Name
Wheelchair, Mechanical 89IOR

Predicate Devices
The product that is substantially equivalent to the Jewel MPS Manual Wheelchair is Invacare's Model Action AT II Manual Wheelchair (K984447).

Intended Use
The intended use of the Jewel MPS Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

Device Description:

The Jewel MPS is a manually operated, attendant propelled, mechanical wheelchair. Its intended function and use is to provide mobility to persons who may be restricted to a sitting position.

The Jewel MPS is a manual wheelchair that is used as an attendant propelled device in a health care environment such as a hospital, nursing home or extended care facility or private home. Its intended function and use is to provide mobility to persons who may be restricted a sitting position.

The product consists basically of the wheelchair frame, seat, larger rear wheels and smaller front pivoting casters for steering and turning.

The wheelchair frame is constructed from both .985" and 1.50" outside square, mechanical, steel tubing. The frame is of welded construction. This device is a rigid, "non folding" type wheelchair that incorporates a custom contoured supportive seating system. This type of seat incorporates an anti-thrust seat front, lateral contouring on both the padded seat and padded backrest. Push handles are located on the back of the backrest for ease of attendant pushing.

The Jewel MPS also includes a "Tilt in Space" feature, which allows the seat and back of the wheelchair to be tilted. This feature is used for those patients who require a tilt feature for stability, comfort or head control. It also serves as an attendant aid in those situations where a patient needs to be tilted to be fed, or attended to in some fashion.

The "Tilt in Space" feature is manually operated and is activated by a foot pedal located at the rear of the wheelchair. Adjusting the tilt is achieved by depress the pedal. When the pedal is pressed down, a hydraulic cylinder attached to the frame and the rear of the seat allows the seat to tilt back. Once the desired tilt angle has been obtained, the pedal is released and the chair will remain at the angle chosen. The chair has a tilt range of 24 degrees.

Substantial Equivalence

The product that is substantially equivalent to the Jewel MPS Manual Wheelchair is; Invacare's Model Action AT II Manual Wheelchair (K984447).

Each of these products is a manually operated, attendant propelled, manual mechanical wheelchair with the same intended function and use which is to provide mobility to persons limited to a seated position. All products consist basically of a mechanical frame to support the wheelchair, large rear wheels, and smaller front pivoting casters for turning and steering. Additionally, each of these wheelchairs incorporates a manually operated "tilt in space" feature for patient comfort and positioning.

Performance Data

NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2001

Mr. Rick Michael
Sales Manager
Vestil Manufacturing Corporation
900 Growth Parkway
Angola, Indiana 46703

Re: K011374
Trade Name: Jewel MPS
Regulation Number: 890.3850
Regulatory Class: I
Product Code: IOR
Dated: May 1, 2001
Received: May 4, 2001

Dear Mr. Michael:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICANT: VESTIL MANUFACTURING COMPANY

510(k) Number (~~if known~~): K011374

Device Name: JEWEL MPS

Indications For Use:

THE INTENDED USE OF THE JEWEL MPS MANUAL WHEELCHAIR IS TO PROVIDE MOBILITY TO PERSONS LIMITED TO A SITTING POSITION.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011374

Prescription Use____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)